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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/021,963 | 12/14/2001 | Darrell C. Conklin | 98-40D1 | 1934 |

7590

11/17/2005

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,963

Applicant(s)

CONKLIN, DARRELL C.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,10,12,14-18 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10, 12, 14-18 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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| Application/Control Number: 10/021,963 | Page 2 |
| Art Unit: 1642 | |

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 9, 10, 12, 14-18 and 20-28 are pending.
Claim 9 has been amended.
Claims 9, 10, 12, 14-18 and 20-28 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections

Specification

3. The disclosure is no longer objected to because the sole drawing and the corresponding brief description of the drawing contains amino acid residues properly identified with a SEQ ID number.

Claim Objections

4. In view of Applicant's arguments and amendment to claim 9, claims 20, 21, 24 and 25 are no longer objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

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| Application/Control Number: 10/021,963 | Page 3 |
| Art Unit: 1642 | |

Withdrawn Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 9, 10, 12, 14-18 and 20-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's arguments.

Maintained and New Grounds of Rejections

Claim Rejections - 35 USC § 112

6. The rejection of claims 9, 10, 12, 14-18 and 20-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicant avers Lederman, Li and Ngo, references supplied with the first action on the merits (FAOM) in support of the instant rejection do not support said rejection, see page 6, 2nd paragraph of Remarks filed September 1, 2005. Applicant also attests Kunitz inhibitors are highly polymorphic and tolerant of amino acid substitutions "...and retain their activity as isolated domains and components of larger proteins..., see last sentence of bridging paragraph on pages 6 and 7. In support of their arguments Applicant provide several references. These references, as well as Applicant's arguments and points of view have been carefully considered, but found unpersuasive. The claim language embodies a peptide encoded by a DNA segment encoding a protein of from 51 to 81 amino acid residues in length, said comprising a *sequence* of amino acid residues of SEQ ID NO: 2 from residue 6 through residue 56. Furthermore,

Art Unit: 1643

claim 9 reads on a segment of DNA encoding a protein, which may be just one or two amino acid residues. Clearly, a couple of amino acid residues cannot reasonably encode the zkun6 protein or the Kunitz domain, which according to Applicants are capable of exerting activities such as usefulness in antithrombotic medicaments, see page 36, line 14-page 37, line 2. The specification does not provide sufficient guidance as to the implementation of an expression vector containing a DNA segment which encodes a protein comprising *a sequence* of amino acid residues of SEQ ID NO: 2 from residue 6 through residue 56. And while Applicant has provided documents, which help substantiate the flexibility and tolerability of Kunitz domains the instant rejection is not obviate in view of the current claims. The documents and the accompanying arguments do not support Applicant's perspective or claims as written because Applicant's claimed invention reads on a protein comprising a couple of residues and this is not commensurate with Applicant's documents and arguments.

It is not clear if a functional product will be produced with the residues set forth in the claims. It is art known that it is highly unlikely a peptide would be produced from the polynucleotide segment that encodes a protein of from 51 to 81 amino acid residues in length, said protein comprising *a sequence* of amino acid residues as presented in SEQ ID NO: 2 from residue 6 through residue 56. Implementation of Applicant's assays and suggested therapies is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. Accordingly, the rejection is maintained.

Art Unit: 1643

7. Claims 9, 10, 12, 14-18 and 20-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims broadly embody an expression vector comprising several operable elements, as well as a DNA segment encoding a protein of from 51 to 81 amino residues in length, said protein comprising a sequence of amino acid residues shown in SEQ ID NO: 2 from residue 6 through residue 56. The written description in this instant case only sets forth a full-length zkun6 polypeptide, SEQ ID NO: 2 consisting of 59 amino acid residues, which comprises a Kunitz domain (residues 6 to 56), see page 5, lines 16-21; page 10, lines 20-27 and Figure 1. The written description is not commensurate in scope with claims drawn to polynucleotide segments encoding a fraction of SEQ ID NO: 2. Nor is the written description commensurate in scope with claims embracing unknown amino acid residues at the beginning and end of amino acid residue 6 through residue 56 of SEQ ID NO: 2.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115). With the exception of SEQ ID NO: 2, the skilled artisan cannot envision the detailed structure or function of the encompassed polynucleotides and polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants only had possession of a full-length DNA that encodes a full-length polypeptide sequence, SEQ ID NO: 2. SEQ ID

Art Unit: 1643

NO: 2 consists of 59 amino acid residues. The specification does not evidence the possession of all the variant polynucleotides that encode polypeptides ranging in length from 51 to 81 amino acid residues. The specification does not present Applicant's possession of nucleic acid molecules encoding mutant polypeptides which have unknown amino- and carboxy-termini that exist at the beginning and ending of amino acid residue 6 through residue 56, respectively. There is insufficient support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

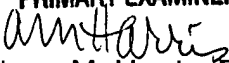
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

14 November 2005